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Applicant Initiated Interview Request Form

Application No.: 10/753892 First Named Applicant: Richard J. Mackool
Examiner: Laura Bouchelle Art Unit: 3763 Status of Application: Final rejection

Tentative Participants:
(1) Robert J. Hess **(2)** Laura Bouchelle

(3) Nicholas D. Lucchesi **(4)**

Proposed Date of Interview: June 27, 2007 (Thursday) **Proposed Time:** 10 AM **(AM/PM)**

Type of Interview Requested:
(1) [x] **Telephonic** **(2)** [ ] **Personal** **(3)** [ ] **Video Conference**

Exhibit To Be Shown or Demonstrated: [ ] **YES** [x] **NO**
If yes, provide brief description:

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) Rej.	1-10	Strukel, Southern	[ ]	[ ]	[ ]
(2)			[ ]	[ ]	[ ]
(3)			[ ]	[ ]	[ ]
(4)			[ ]	[ ]	[ ]

[ ] Continuation Sheet Attached

Brief Description of Arguments to be Presented:
Southern is non-analogous art that is not reasonably pertinent to problems faced by the inventor. Difference in claim language between claims 5 and 11 not so great as to warrant rejection of claim 5 over prior art since claim 11 is deemed allowed. See sheets attached.

An interview was conducted on the above-identified application on _____.
NOTE: This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).
This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

Robert Hess
Applicant/Applicant's Representative Signature — Examiner/SPE Signature

Robert J. Hess
Typed/Printed Name of Applicant or Representative

32,139
Registration Number, if applicable

Points to be raised during the Examiner interview.

1) Paragraph 6 of the final Office Action is incomplete that reads

> *Southern discloses that this formation prevents the occlusion of fluid flow during.*

Southern mentions in col. 1 line 11-19:

> *However, a recurring problem in catheters used to collect blood samples is that the catheter tip can become blocked when negative pressure is applied to draw blood. When blockage of the catheter occurs, the patient must be re-punctured to collect a new blood sample. The primary cause of blockage is adherence of the catheter tip to the sides of the vessel walls, thus preventing the return of blood flow. An additional cause of blockage is a blood clot that blocks the catheter tip.*

Therefore, it is uncertain whether the incomplete sentence should read: Southern discloses that this formation prevents the occlusion of fluid flow during **the application of negative pressure to draw blood, which occlusion results from adherence of the catheter tip to the sides of vessel walls that prevent the return of blood flow or from a blood clot that blocks the catheter tip**.

2) Southern is non-analogous art that is not properly relied upon to justify an obviousness rejection. Southern is concerned with providing a non-planar shape, such as a V-shape tip, at the distal end of a blood flow catheter. The present invention is concerned with providing peak and valley formations at the end of an irrigation sleeve of a phacoemulsification instrument. Thus, Southern constitutes non-analogous art.

While it is recognized that even non-analogous art is justifiably applied in an obviousness rejection where it is reasonably pertinent to the particular problem with which the inventor was concerned, such has not the situation with Southern. MPEP 2141.01(a). The present inventor clearly was not concerned about **the application of negative pressure to draw blood, which occlusion results from adherence of the catheter tip to the sides of vessel walls that prevent the return of blood flow or from a blood clot that blocks the catheter tip**.

Such has nothing to do with addressing the problem of heat buildup at the region where the phacoemulsification needle penetrates the incision.

Southern further provides:

> *If the terminal end of the catheter becomes lodged against the blood vessel wall, blood flow is maintained because the non-planar shape of the catheter tip prevents total blockage since its shape does not allow it to form a seal with a blood vessel wall. Thus, re-catheterizing a patient is prevented or greatly reduced.*

The present inventor did not face the problem of a catheter becoming lodged against a blood vessel wall or about maintaining blood flow. Indeed, the inventor did not have to the tackle the problem of total blockage from a seal formed with a blood vessel wall or about preventing or greatly reducing re-catheterizing a patient.

Instead, the inventor faced three problems. The first was to accommodate entry of an ultrasonic needle into the eye through an incision smaller than can accommodate the ultrasonic needle together with a surrounding irrigation sleeve (see paragraphs [0002] and [0003]). The second was to take away heat buildup during phacoemulsification before it becomes excessive that would result in incision wall tissue damage (see paragraphs [0005] and [0006]). The third was to maintain irrigation flow to the distal end of the irrigation sleeve that would otherwise become

stagnant where the distal end of the irrigation sleeve is planar and sealed against the exterior incision wall (see paragraph [0010]).

Neither Strukel nor Southern tackle the first problem. The incision in Strukel is large enough to accommodate penetration by both the needle and surrounding irrigation sleeve --thereby requiring more time to heal after the surgical procedure ends that would be the case for a smaller size incision. Southern pertains to catheter blood flow and thus has nothing to do with phacoemulsification.

Neither Strukel nor Southern tackle the second problem. Indeed, Strukel does not need to convey heat buildup away since it avoids any heat buildup by creating a barrier between the needle and the incision wall in the form of the irrigation sleeve penetrating the incision to convey irrigation fluid. Thus, there is no opportunity for heat buildup at the incision. Southern is concerned with blood flow catheters, which have nothing to do with removing heat buildup before it becomes excessive.

Neither Strukel nor Southern tackle the third problem. In the case of Strukel, the distal end of its irrigation sleeve remains clear of the incision wall since it is inserted beyond it. In the case of Southern, it is concerned about taking steps to avoid sealing the distal end of its catheter (as opposed to a phacoemulsification irrigation sleeve) against a blood vessel wall or blood clot (as opposed to against an incision wall). Southern is concerned with maintaining return blood flow, as opposed to irrigation fluid flow at an eye incision.

Southern is not concerned about using catheters to prevent heat buildup anywhere (and certainly would not rely on blood flow for such a purpose), but instead about preventing or greatly reducing recatheterization. Indeed, Southern is concerned about blockage of its catheter against blood vessels, because such blockage blocks blood flow. However, blockage from blood vessels is not a concern to either Strukel or the present invention, both of which have nothing to do with catheters or maintaining blood flow. As such, there is no showing that Southern is reasonably pertinent to the

problems faced by the inventor and is not properly relied upon to justify an obviousness rejection.

3) Justify how the difference in the recitations of claims 5 and 11 warrant rejection of claim 5 over Strukel and Southern, but not claim 11. The differences in language between the claims is highlighted in bold in the following comparison table.

Claim 5 (previously presented): A method of **cooling**, comprising extending a needle within confines of an infusion sleeve that is hollow and projecting a tip of the needle outwardly beyond a distal end of the infusion sleeve, defining a passage between an interior surface of the infusion sleeve and an exterior surface of the needle, terminating the infusion sleeve at the distal end by peak and valley formations, arranging the valley formations closer to a proximal end of the infusion sleeve than are the peak formations, and abutting an exterior of an incision with the peak formations of the infusion sleeve**; and** flowing fluid through the passage to the distal end of the infusion sleeve **to** thereafter **flow** across the valley formations, the needle defining an interior channel, the infusion sleeve being elongated between the proximal and distal ends and being made of a flexible material that is collapsible and expandable axially as the needle is repetitively partially withdrawn and advanced.	Claim 11 previously presented): A method of **preparing to cool**, comprising: extending a needle within confines of an infusion sleeve that is hollow and projecting a tip of the needle outwardly beyond a distal end of the infusion sleeve, defining a passage between an interior surface of the infusion sleeve and an exterior surface of the needle, terminating the infusion sleeve at the distal end by peak and valley formations, arranging the valley formations closer to a proximal end of the infusion sleeve than are the peak formations, and abutting an exterior of an incision with the peak formations of the infusion sleeve **so that** flowing fluid through the passage to the distal end of he infusion sleeve **and away from the proximal end results in the fluid** thereafter **flowing** across the valley formations, the needle defining an interior channel, **and** the infusion sleeve being elongated between the proximal and distal ends and being made of a flexible material that is collapsible and expandable axially as the needle is repetitively partially withdrawn and advanced.